

REMARKS

Claims 7, 10 and 24-33 are pending in the present application. Claims 7, 10, 30, 32 and 33 have been amended, claims 29 and 31 have been cancelled, and claims 34 and 35 have been added, leaving Claims 7, 10 and 24-28, 30, 32-35 for consideration upon entry of the present amendment.

Claims 7 and 10 have been amended to include the limitations of claims 29 and 31.

Claims 30, 32 and 33 have been amended to change their dependency.

Support for new claims 34 and 35 can be found in the examples, such as example 4 in which the entire contents of the reaction product is used as an animal food flavorant.

Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

As a preliminary note, Applicants respectfully point out that Dr. Chi-Tang Ho has previously worked as a consultant for AFB International, and Dr. Deborah Roberts has been a consultant for AFB International for the last three years.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 7, 10 and 24-33 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,079,017 to Chen (hereinafter “Chen”) in view of U.S. Patent No. 4,267,195 to Boudreau et al. (hereinafter “Boudreau”) and U.S. Patent No. 6,312,746 to Paluch et al. (hereinafter “Paluch”). Applicants respectfully traverse the rejection.

The present claims are directed to a palatability enhancer for an animal food and an animal food product both comprising a reaction product, wherein the reaction product is produced from at least one triglyceride molecule and at least one donor which functions as a donor of elements selected from the group consisting of sulfur, nitrogen, and a combination of sulfur and nitrogen. The reaction product is made by cooking at ambient pressure and a temperature of about 90°C to about 98°C, or cooking at a pressure of greater than 10 pounds per square inch and a temperature of about 110°C to about 200°C. The claimed palatability enhancer comprises a “cooked product”, that is a reaction product formed between the fat/oil and the donor. The palatability enhancer comprises least one second palatability enhancer ingredient prepared by hydrolytic fermentation of at least one type of cohesive animal tissue.

Chen is directed to a flavoring composition prepared by heating a fat or oil to a temperature of 300°C to 475°C. (Abstract) The volatile fractions are collected as flavorants. (Abstract) Flavor precursors including “sulfur-containing compounds such as cysteine, cystine, methionine, thiamine, hydrogen sulphide, or sulfur-containing extract from vegetables” may be employed during heating of the fat. (col. 2, ll. 41-43) The flavoring composition can be used to impart flavors to “meats, sauces, soups, etc.”. (col. 3, ll. 48-49) There is no mention in Chen of the use of the flavoring compositions in an animal food.

Boudreau is directed to dog food flavors containing “L-proline, L-cysteine, L-histidine, L-lysine, inosine 5'-triphosphate (ITP), inosine 5'-diphosphate (IDP), and adenosine 5'-triphosphate (ATP)”. (Abstract) The use of these compounds in dog foods can “increase their palatability to dogs”. (Abstract) The flavors can be “applied to the exterior of the fat coating” or incorporated into the dog food by “simple mixing with the other ingredients”. (col. 2, ll. 42-46) There is no description of heating or in any way reacting the L-cysteine, etc.

Paluch is directed to a multi-component pet food having inner and outer components. (Abstract) The filling may comprise, for example, hydrolyzed meat protein. (col. 10, l. 61)

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

In order to further prosecution, and to further distinguish the presently claimed reaction flavors from those disclosed in Chen, the present claims have been amended to add the limitation of cooking at “ambient pressure and a temperature of about 90°C to about 98°C”, or “at a pressure of greater than 10 pounds per square inch and a temperature of about 110°C to about 200°C”. These temperature/pressure combinations are not taught in Chen, thus these elements of the present claims are not taught or suggested by the prior art. Thus, the presently claimed reaction flavors are distinct from those taught in Chen.

Further, one of skill in the art would not modify Chen to change the reaction temperatures for several reasons. First, different reaction temperatures produce different flavors, thus changing the temperature will change the flavor notes produced. Second, Chen is specifically directed to collecting the volatile fractions of the reaction. The molecules of interest may not be volatile at the lower temperatures. Thus, Chen provides no motivation to alter the temperatures disclosed therein and no expectation of success for such a modification.

In order to clarify the differences between the presently claimed reaction products, and those disclosed in Chen, Applicants submit a Second Declaration by Dr. Deborah Roberts (attached herewith). In this declaration, Dr. Roberts explains the differences between the temperatures disclosed in Chen and those disclosed in the present application as follows:

As is well-known to those of skill in the art and as disclosed in Chen, the types of reaction products and the amounts of individual species produced in a reaction flavor is highly dependent on the temperature employed. One would not expect a reaction performed at 300 to 475°C to produce the same flavors as a reaction performed at 110 to 200°C. General physical chemical principles state that at 10°C change in a reaction temperature will double the rate of the reaction. Not only is the rate accelerated at 400°C, but also the types of compounds produced are very different, as different chemical pathways will be taken.

(Second Roberts Declaration, signed May 22, 2006, Page 3)

Another difference between Chen and the present application is that Chen teaches the use of volatile distillates only while the present application teaches the use of a mixture comprising solid materials.

For animal palatability, there is a large difference between volatile distillates (Chen) and a more complex mixture containing solid materials (Nelles). It is similar to comparing the smell of beef to the full flavor experienced when eating beef. The complex mixture contains non-volatiles (tastants) as well as volatile compounds. Dogs and cats respond to non-volatile compounds, as they have specific receptors on their tongue. Dogs, for example, respond to non-volatiles such as sugars or nucleotides that would not be contained in Chen's volatile distillates. The Chen flavor and the Nelles flavor are very different in composition and in dog palatability impact. In conclusion, the palatability of distillates of a reaction performed at 300 to 475°C is no way predictive of the palatability of a whole reaction performed at 110 to 200°C, to either humans or animals.

(Second Roberts Declaration, signed May 22, 2006, Pages 3-4)

Thus, the claims as presently presented can be clearly distinguished from the disclosure of Chen at least because of the claimed reaction temperatures. As explained previously and in the Second Roberts Declaration, the temperature of the reaction has a large influence on the types of products and this on the flavor produced. As here, a difference in reaction temperature of greater than 100°C would have a large effect on the reaction products produced. Also of note is that Chen is specifically directed to collecting the volatile fractions produced in the reactions for use as flavorants. In the present application, no such isolation of volatile materials is required.

Regarding the suitability of the flavor compositions of Chen in animal foods, and as explained previously, Chen does not test their flavor compositions on animals and thus it is not possible to know, from the disclosure of Chen, if the flavor compositions are suitable for use on animal foods. The flavor compositions of Chen may not be effective on an animal food, particularly a dry animal food such as a kibble. The disclosure of a flavorant for human food does not render obvious the use of that flavorant as a palatant for animal foods. One of skill in the art would not combine Chen, directed to flavors for human food, with either Bodreau and/or Paluch, which are directed to flavors for animal foods. In the absence of testing such a combination on animals, there can be no expectation of success for the combination.

In addition, due to the differences in the chemical nature of the palatants described in both Chen and Bodreau, one of skill in the art would not be motivated to combine these references. Chen is directed to flavors that are produced by reaction of fat and, for example, cysteine at temperatures of 300°C to 475°C. The flavors of Chen are not cysteine itself, but a reaction product formed between cysteine and fat. Bodreau teaches the use of cysteine as a flavorant in pet food, not a reaction product. One would not, without further testing, simply substitute the reaction product of Chen for the cysteine of Bodreau. Reaction products and cysteine are different molecules having different flavoring properties. Thus, the references provide no motivation for making the substitution suggested by the Examiner. Further, there is no expectation of success for such a substitution as the references provide no teaching that the compositions containing a reaction product as in Chen would be palatable to animals in a flavoring or food composition for animals.

Applicants further submit that Paluch does not cure the defects of Chen and Bodreau. Paluch is directed to a pet food, which may comprise ingredients such as a hydrolyzed animal

digest. Paluch, however, does not describe the combination of a reaction flavor such as that taught in Chen and a hydrolyzed animal digest as presently claimed. As stated above, the cited references do not provide the motivation to employ the human food flavorant of Chen in animal food flavors. By the same reasoning, one of skill in the art would not combine the human food flavorant of Chen with a hydrolyzed animal digest, an ingredient use in animal foods. Without proper animal testing, it is therefore not possible to know if a combination of flavors is palatable to an animal. The references not provide the motivation to use the reaction flavor of Chen in a pet food in combination with a hydrolyzed animal digest and further does not provide an expectation of success for such a combination.

In the February 14, 2006 Advisory Action, the Examiner states “The declarations do not specifically compare the art relied upon”. (February 14, 2006 Advisory Action, page 2) Also, the Examiner states that the “flavorant of Chen et al does not exclude application to animals” and “meat flavors are used in animal foods”. (February 14, 2006 Advisory Action, page 2) Applicants respectfully traverse the rejection.

In the Advisory Action, the Examiner has suggested that the previously submitted declarations do not compare the prior art relied upon. With regard to the previously submitted declarations, these declarations do compare to the art relied upon. First, the declaration of Dr. Chi-Tang Ho stated:

Chen et al. do not test their flavor compositions on animals and thus it is not possible to know, from the disclosure of Chen, if the flavor compositions are suitable for use on animal foods. The flavor compositions of Chen may not be effective on an animal food, particularly a dry animal food such as a kibble. The disclosure of a flavorant for human food as in Chen does not render obvious the use of a palatant for animal foods.

(Declaration of Dr. Chi-Tang Ho, dated January 5, 2006, page 2)

The declaration of Dr. Ho clearly identifies Chen as lacking disclosure relating to the suitability of the disclosed flavor compositions for palatability to animals as well as suitability for use in animal foods.

Second, the declaration of Dr. Ho specifically explains that the flavors disclosed in Chen are reacted at temperatures of about 300°C to 475°C and are thus reaction products. (Declaration of Dr. Chi-Tang Ho, dated January 5, 2006, page 3) Dr Ho then goes on to state “Boudreau, in contrast to Chen, teaches the use of cysteine in an animal food. One of skill in the art of flavor

science would not use a reaction product of cysteine and fat to replace cysteine.” (Declaration of Dr. Chi-Tang Ho, dated January 5, 2006, page 3) Thus, the declaration of Dr. Ho directly addresses the prior art and that one of skill in the art would not combine the reaction flavor of Chen with the food compositions of Boudreau due to the differences in the chemical nature of cysteine and the flavors disclosed in Chen.

Third, the declaration of Dr. Ho also addresses the combination of Chen and Boudreau with Paluch, stating:

in the absence of animal testing, it is not possible to predict if a flavor would be appealing to an animal. Further, combinations of flavors may have synergistic or antagonistic effects. Without proper animal testing, it is not possible to know if a combination of flavors is palatable to an animal. Without testing, one of skill in the art would not combine the reaction flavor of Chen with an animal digest as in Paluch.

(Declaration of Dr. Chi-Tang Ho, dated January 5, 2006, page 3)

Dr. Ho clearly states that one of skill in the art would not make a combination as suggested by the Examiner without animal testing or some independent verification of the utility of such a combination.

Third, while the declaration of Dr. Deborah Roberts does not specifically address the references cited by the Examiner, this declaration does set out the differences in taste perception between animals and humans and also explains in detail what a reaction flavor is. This information is relevant to the present claims.

Thus, the Examiner’s comment that the previously submitted declarations do not compare to the art relied upon is not entirely accurate.

Regarding the Examiner’s comments that the “flavorant of Chen et al does not exclude application to animals” and “meat flavors are used in animal foods”, the declaration of Dr. Ho is relevant to address this point. (February 14, 2006 Advisory Action, page 2) This declaration specifically explains that the Chen reference cited by the Examiner provides no guidance as to whether the flavors disclosed therein would be suitable for use on an animal food. Further, while the Examiner states that the “use of a composition is not afforded any patentable weight”, the Examiner’s attention is directed to claim 7 and the claims that depend therefrom. This claim is directed to the combination of a reaction flavor and an animal digest. Such animal digests are typically used as flavors in animal foods. Thus, the intended use is relevant to the claimed

Further, Claim 10 is directed to "An animal food product, comprising a dry or semi-dry animal food prepared by a method selected from the group consisting of pelleting, extruding, or molding, and which has on at least some of its surfaces a palatability enhancer for an animal food created by a method comprising the steps of...". Clearly the reaction product should be suitable for use in an animal food if it is to be included in an animal food. Thus, for Claim 10 and the claims that depend therefrom, the intended use is critical. As explained by Dr. Chi-Tang Ho, there is no teaching in Chen that would suggest that the flavors described therein would be suitable for use on an animal food, particularly a dry animal food such as a kibble.

Chen et al. do not test their flavor compositions on animals and thus it is not possible to know, from the disclosure of Chen, if the flavor compositions are suitable for use on animal foods. Obviousness may be rebutted by a showing of "unexpected results", i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990). The results must be of both statistical and practical significance. *Ex parte C*, 27 U.S.P.Q.2d 1492, 1497 (Bd. Pat. App. & Int. 1993).

In the present case, the Applicants' examples clearly show unexpected results regarding the palatability of the claimed reaction flavors. In Example 1, a reaction flavor formed from reacting sodium sulfide, anhydrous butter oil, and yeast is added to a digest of chicken livers and coated onto a dog food. Compared to the digest of chicken livers alone, the combination of the reaction flavor and the hydrolyzed chicken livers improves palatability 2-3-fold when dogs were tested in a 2-bowl comparison. Similar results were obtained in Examples 2-5 for reaction flavors formed using sodium sulfide and chicken fat. There is nothing in the prior art that would suggest that the presently claimed reaction flavors would improve palatability to dogs, particularly in the presence of a hydrolyzed liver digest which is a known palatability enhancer for dogs. It is not expected that combining a reaction flavor with another flavorant would improve palatability to animals.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any charges with respect to this Amendment, or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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DECLARATION UNDER 37 CFR 1.132

Dr. Deborah Roberts declares and says that:

1. I graduated from Cornell University with a Ph.D. Degree in Food Science in January 1996. From 1996 to 2002, I have been employed as a research flavor chemist for Nestle S.A. From 2003 until 2006, I have been employed as a consultant to the food and flavor industries for Food and Flavor Science Consulting LLC. I have greater than 10 years experience as a flavor chemist.
2. For the past 3 years, I have been a consultant for AFB international.
3. I have read the above-referenced U.S. patent application, herein referred to as "the application".
4. I have reviewed the Advisory Action dated February 14, 2006 and U.S. Patent No. 5,079,017 to Chen et al. (hereinafter "Chen").

5. Chen is directed to a process for obtaining flavors by distilling a fat or oil at a temperature from 300° to 475° C for prolonged periods in a special batch type apparatus and collecting the volatiles. (Abstract; Col. 1, ll. 37-44). Flavor precursors such as sulfur-containing compounds can be added to the fat or oil prior to heating. (Col. 2, ll. 39-41) Chen also discloses that the batch type apparatus should be capable of withstanding the high temperatures involved in their process, and a bomb reactor is particularly suitable. (Col. 2, ll. 8-10; Fig. 1). Chen further discloses that the batch type apparatus is provided with a cold trap or condenser for the collection of the volatiles produced in the reaction. (Col. 2, ll. 4-5).

6. Chen teaches that the volatiles obtained by their process are distinct from the volatiles obtained by other processes that heat a fat or oil at lower temperatures. For example, Chen teaches that the flavors formed by the process disclosed therein are distinct from those formed by heating animal fat with brewed soy sauce at a temperature of 130-220°C as disclosed in US PN 4,4,094,997. (Col. 1, ll. 44-52). Chen clearly teaches that the flavor notes that are produced depend upon factors including the temperature of the reaction, the flavor precursors employed, and the time of reaction. (Col. 3, ll. 6-12). As shown, for example, in Example 1, even different volatile fractions have different flavors. (Col. 4, ll. 40-49).

7. Chen also teaches that only the distillates formed by the reaction should be retained, with the remaining solid materials left behind in the reactor. (Col. 2, l. 65- Col. 3 l. 5).

8. The claims of the present application are directed to palatability enhancers for animal food. The present invention is directed to reacting a liquefied mixture of triglycerides with a sulfur and/or nitrogen containing compound at “a pressure of greater than 10 pounds per square inch and a temperature of about 110°C to about 200°C”. The claimed method does not comprise either the step of heating at a temperature of 300° to

475°C or the step of distillation to collect volatiles.

9. As is well-known to those of skill in the art and as disclosed in Chen, the types of reaction products and the amounts of individual species produced in a reaction flavor is highly dependent on the temperature employed. One would not expect a reaction performed at 300 to 475°C to produce the same flavors as a reaction performed at 110 to 200°C. General physical chemical principles state that at 10°C change in a reaction temperature will double the rate of the reaction. Not only is the rate accelerated at 400°C, but the types of compounds produced are very different, as different chemical pathways will be taken. For example, a study on sesame oil with different roasting temperatures found that acids and free fatty acid contents decreased at levels above 220°C<sup>1</sup>. Free fatty acids, such as butyric acid, are also known to be palatability enhancers for dogs. They also found that phenols increased at temperatures above 210 °C and compounds with high retention indices decreased with temperatures above 230 °C. Another study with perilla oils found that roasting temperature significantly affected the production of thermal reaction flavor compounds<sup>2</sup>. Roasting the oil under 170 °C had relatively high concentrations of aldehydes whereas roasting above 170 °C showed predominantly pyrazines and furans. In addition, pyrolysis, which is a form of incineration, may occur at temperatures of 300 to 475°C.

9. For animal palatability, there is a large difference between volatile distillates (Chen) and a more complex mixture containing solid materials (Nelles). It is similar to comparing the smell of beef to the full flavor experienced when eating beef. The complex mixture contains non-volatiles (tastants) as well as volatile compounds. Dogs and cats respond to non-volatile compounds, as they have specific receptors on their tongue. Dogs, for

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1. H-W. Kim, K-M. Park, C-U. Choi. 2000. Korean J. of Food Sci. and Technol. 32(2), p. 238-245, "Studies on the Volatile Flavor Compounds of Sesame Oils with Roasting Temperature".

2. S.J. Kim, H.N. Yoon, J.S. Rhee. 2000. J.A.O.C.S. 77(4), p. 451-456, "The Effects of Roasting Temperatures on the Formation of Headspace Volatile Compounds in Perilla Seed Oil."

example, respond to non-volatiles such as sugars or nucleotides<sup>3</sup> that would not be contained in Chen's volatile distillates. The Chen flavor and the Nelles flavor are very different in composition and in dog palatability impact. In conclusion, the palatability of distillates of a reaction performed at 300 to 475°C is no way predictive of the palatability of a whole reaction performed at 110 to 200°C, to either humans or animals.

9. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

Date: May 20, 2006

Deborah Roberts

Dr. Deborah Roberts

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3. T. Kumazawa, M. Nakamura, K. Kurihara. 1991. Physiology and Behavior. 49, p. 875-881, "Canine Taste Nerve Responses to Umami Substances".